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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: SEFTON

Serial No.: 09/367,712

Filed: August 18, 1999

For: TAZAROTENE AND CORTICOSTERIOD TREATMENT FOR PSORIASIS

Examiner: BADIO

Group Art Unit: 1616

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on:

Date of Deposit: 5/8/2001

Print Name: Bonnie Ferguson

Signature: Bonnie Ferguson

Date of Signature: 5/8/2001

REPLY BRIEF UNDER 37 CFR §1.193

Assistant Commissioner For Patents
Washington, D.C. 20231

Sir:

In response to the Examiner's Answer of March 8, 2001, the Applicant has the following statements and remarks.

(1) Real Party in Interest

The Real Party in Interest is **ALLERGAN SALES, INC.**, the owner at the time the brief was filed.

(2) Related Appeals and Interferences

There are no related appeals and interferences which will directly affect or be

directly affected by or have a bearing on the decision in the pending appeal contained in the brief.

(3) Status of Claims

Claims 1-3, 5-8 and 10-13 are pending and have been rejected under 35 USC §103 as being obvious. Claims 4 and 9 have been canceled.

(4) Status of Amendments After Final

The statement of the status of amendments after final rejection contained in the appeal brief is correct:

(5) Summary of Invention

The summary of invention contained in the appeal brief is correct:

(6) Issues

The statement of the issues in the appeal brief is correct.

(7) Grouping of Claims

Group I, Obviousness includes claims 1-3, 5 and 12

Group II, Obviousness includes claims 6-8, 10 ,11, and 13

The claims within each group do not stand or fall together. The statement and supporting arguments are given in the paragraph commencing on page 7 and continuing on page 8 of the appeal brief.

(8) Arguments

The Rejection of the Claims of Group I under 35 USC § 103

The Examiner has rejected claims 1-3, 5, and 12 under 35 USC § 103 as being unpatentable over Yamamoto '906 and Nagpal et al. '279 in combination. Claim 2 has been rejected under 35 USC § 103 as being unpatentable over Smith '074 or Sequeira et al. '529 in combination with Nagpal et al '279.

The Examiner has argued that:

Smith '074 and Sequeita et al. '529 disclose a method of treating skin disorders with the use of **any corticosteroids**

Nagpal et al. '279 disclose a method of treating psoriasis with tazarotene.

Yamamoto '906 discloses the use of **any adrenocortical hormone** in the treatment of skin disease.

There is no motivation found in any of the references for the combination of tazarotene and a corticosteroid. Yamamoto '906 does not indicate any differences in treatment outcome with varying potency of the 'suggested' corticosteroids. Yamamoto '906 teaches away from the use of corticosteroids at the usual clinical doses in combination with active ingredients. As an example, an effective and usual concentration of fluocinonide (high potency corticosteroid) is 0.05%. This concentration causes irritation and the Yamamoto '906 dilutes this concentration to 0.015% or 0.005% to reduce the adverse corticosteroid-induced effects. There is no suggestion of selecting only certain mid- to high-potency corticosteroids (See selected mid- and high-potency corticosteroids of claim 2) to combine with an additional active antipsoriasis agent to obtain unexpected results for the treatment of psoriasis.

The two working examples in the specification (page 10, line 9 and page 13, line 7) further support Claim 2 as the data illustrated that the treatment with the high potency corticosteroid, fluocinonide, achieved a higher treatment success rate (75%) and faster

initial treatment success (2 weeks as compared to 4 weeks).

The Rejection of the Claims of Group II under 35 USC § 103

The Examiner has rejected claims 6-8, 10, 11 and 13 under 35 USC § 103 as being unpatentable over Yamamoto '906 and Nagpal et al. '279 in combination.

The Applicant has demonstrated that mid- or high-potency corticosteroids in combination with tazarotene exhibit a synergistic effect that provides a more effective treatment of psoriasis than tazarotene, alone, or with a low-potency corticosteroid. (See lines 20-23 of page 9 of the present specification.).

The unpredictable results for the combination of the mid- or high-potency corticosteroids with tazarotene are given in Example 1. (See page 10, line 28 through page 11, line 5 of the present specification and Figure 1.) Based on effectiveness of each individual component and the synergistic effect of the combination of the two components in an unpredictable technology (Testing of the combinations was required to demonstrate effectiveness or lack thereof), there is no prima facie obviousness of unpredictable results. It is less likely that structurally similar species will render a claimed species obvious in an unpredictable technology, because it may not be reasonable to infer that the species would share similar properties.

The data provided in Example I showed that tazarotene/high potency combination achieved a success rate of 75% and tazarotene/mid potency combination had a success rate of $\geq$ 60% in clinical improvement in psoriasis. The unexpected and surprising finding was the decrease in overall incidence of adverse events with increased corticosteroid potency. In Example II (page 13, line 7 through line 17), the use of tazarotene in combination with either a mid (mometasone furoate) or a high potency (fluocinonide) corticosteroid was associated with a higher success treatment rate along with a decreased incidence of adverse effects. Figure 2 in the present specification illustrates clearly the unexpected and unpredictable success of use of the high-potency corticosteroid, both during and after the treatment period.

In view of the above, the Board is asked to reverse the Examiner's holding of all of the pending claims in Group I or in Group II as unpatentable and direct the Examiner to pass the claims in to issue.

Respectfully submitted,

Date: May 8, 2001

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